UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,437	12/17/2001	Stephen A. Johnston	5171-00041	2358

7590 02/08/2007

ANDRUS, SCEALES, STARKE & SAWALL, LLP
Suite 1100
100 East Wisconsin Avenue
Milwaukee, WI 53202

EXAMINER	
FORD, VANESSA L	
ART UNIT	PAPER NUMBER
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/023,437	JOHNSTON ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26,27,29-38,50-61,74,76-81,92-95 and 104-121* is/are pending in the application.

4a) Of the above claim(s) *26-27, 29-38, 50-61 and 76-81* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *74,92-95 and 104-121* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is responsive to Applicant's response filed October 31, 2006. Claims 1-2, 28, 62-73, 75, 82-91 and 96-103 have been cancelled. Claims 26-27, 29-38, 50-61 and 76-81 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 116-121 have been added.

Rejections Withdrawn

2. In view of Applicant's amendment and remarks the rejection the following rejections are withdrawn:

a) rejection of claims 92 and 96-99 under 35 U.S. C. 112, first paragraph, pages 2-6, paragraph 3 of the previous Office action.

b) rejection of claims 25, 39, 41-45, 74 and 83 under 35 U.S. C. 102(e), pages 6-9, paragraph 4 of the previous Office action.

c) rejection of claims 25, 39, 41-45, 74 and under 35 U.S. C. 102(b), pages 9-12, paragraph 5 of the previous Office action.

d) rejection of claims 25, 39, 41-45, 74, 83 and 92-115 under 35 U.S. C. 112, first paragraph, pages 13-14, paragraph 6 of the previous Office action.

e) rejection of claim 25 under 35 U.S. C. 112, second paragraph, page 14, paragraph 7 of the previous Office action.

f) rejection of claims 92, 94 and 95 under 35 U.S. C. 112, second paragraph, page 14, paragraph 8 of the previous Office action.

g) rejection of claims 96, 100 and 107 under 35 U.S. C. 112, second paragraph, pages 14-15, paragraph 9 of the previous Office action.

h) rejection of claims 97 and 101 under 35 U.S. C. 112, second paragraph, page 15, paragraph 10 of the previous Office action.

i) rejection of claims 98 and 102 under 35 U.S. C. 112, second paragraph, pages 15, paragraph 11 of the previous Office action.

j) rejection of claims 99 and 103 under 35 U.S. C. 112, second paragraph, pages 15-16, paragraph 12 of the previous Office action.

k) rejection of claims 92-115 under 35 U.S. C. 112, second paragraph, pages 16, paragraph 13 of the previous Office action.

m) rejection of claims 92 and 94 under 35 U.S. C. 112, second paragraph, page 16, paragraph 14 of the previous Office action.

n) rejection of claims 93 and 95 under 35 U.S. C. 112, second paragraph, pages 17, paragraph 15 of the previous Office action.

o) rejection of claims 25, 41-43, 74, 83, 92-106 and 113-115 under 35 U.S. C. 112, second paragraph, pages 17-18, paragraph 16 of the previous Office action.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 74, 92-95 and 104-121 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are direct to a method of immunizing an animal comprising the steps administering a *Chlamydia psittaci* antigen to an animal in an amount effective to induce

an immune response against *Chlamydia psittaci* wherein the *Chlamydia psittaci* antigen comprise the amino acid sequence as set forth as SEQ ID NO:7, SEQ ID NO:9 SEQ ID NO:11 and SEQ ID NO:13 (sequences examined with regard to the claimed invention).

The instant specification teaches that SEQ ID NO: 7 (CP4#1) is a polypeptide translation corresponding to SEQ ID NO:6 homolog to *Chlamydia pneumoniae* DNA POL III Gamma and TAU subunits. The specification teaches that SEQ ID NO: 9 (CP4#1) is a polypeptide translation corresponding to SEQ ID NO:8 homolog to *Chlamydia pneumoniae* DNA POL III Gamma and TAU subunits. SEQ ID NO: 11 (CP4#2) is a polypeptide translation corresponding to SEQ ID NO:10 homolog to *Chlamydia pneumoniae* Glu-tRNA Gln Anido-transferase (C subunit) (gatC gene) and SEQ ID NO:13 is (CP4#2) is a polypeptide translation corresponding to SEQ ID NO:12 homolog to *Chlamydia pneumoniae* Glu-tRNA Gln Anido-transferase (C subunit) (gatC gene).

The instant specification discloses in Examples 5-12 experimental examples using *Chlamydia* nucleic acid molecules and polypeptides used to immunize animals. The specification refers Figures 4- 8 which disclose the data from the various experimental examples. Regarding figure 5, which are the results of protection assays of testing individual gene fragments in found 4 (page 15). The specification teaches that protection was scored as lung weight relative to the average of the vaccinate, maximum protection, positive control (vaccinated =1) and the non-vaccinated, challenged, maximum disease, negative control (challenged=0). It is unclear as to what Applicant intends by the data presented in Figure 5. The instant specification presents

data in terms of maximum protection. Applicant does not present an unvaccinated control. Thus, one of skill in the art cannot interpret Applicant's data as set forth regarding protection assays with data from an unvaccinated control. It is unclear as to what the data present in figure 5 actually discloses. The skilled artisan cannot drawn in conclusive evidence from the data presented in the instant specification.

The structure of the elected sequences (SEQ ID Nos 7 and 9) have 48.4% and 64.4% sequence identity, respectively with the DNA polymerase III gamma and tau family of polypeptides from *Chlamydia pneumoniae.* See the sequence alignments below:

SEQ ID : 7, DNA polymerase III gamma and tau [imported] – Chlamydia pneumoniae (strain J138)
Query Match 48.4%; Score 369.5; DB 2; Length 442;
Best Local Similarity 56.2%; Pred. No. 2.6e-28;
Matches 81; Conservative 21; Mismatches 33; Indels 9; Gaps 3;

```
Qy       3 IRTQKYAEALLPVTTAINSGVAPITFLHDLTVFYRDVLLNKDQGNSPLSAIAMHYSSECL 62
           | : || ||  ||  :||||||:|||||||:|||::||    ||  |  :  | :| |
Db     260 ILQRDYATALGIVTDFLNSGVAPVTFLHDLTLFYRNLLLT----NSTTSKFSSQYKTEQL 315

Qy      63 LEIIDFLGEAAKHLQQTIFEKTFLETVIIHLIRICQRPSLETLFSQLKTSTFDTVRNVPQ 122
           |||||||||:|||||  ||||:|||||||||:||| |||  |  | | :|:  |: :||: :
Db     316 LEIIDFLGESAKHLQNTIFEQTFLETVIIHIIRIYQRPVLSELISSIKSRQFEGLRNIKE 375

Qy     123 ---QQEPSKPSIQPEKHYQDQSFL 143
              |: | |  ||:  |::||||
Db     376 PTLTQQVSAP--QPQPTYKEQSFL 397
```

SEQ ID NO:9: DNA polymerase III gamma and tau - Chlamydia pneumoniae (strains CWL029 and AR39)

Query Match 64.4%; Score 1443; DB 2; Length 442;
Best Local Similarity 66.8%; Pred. No. 1.9e-93;
Matches 298; Conservative 48; Mismatches 88; Indels 12; Gaps 4;

```
Qy       1 MTSATYQVSSRKYRPQTFAEMLGQDAVVTVLKNALQFQRVAHAYLFSGIRGTGKTTLARI 60
           ||  || |||||||| | |:||| :|| |||||| | | ||||||||||||||||||||
Db       1 MTLQPYQASSRKYRPQIFREILGQSSVVAVLKNALVFNRAAHAYLFSGIRGTGKTTLARI 60

Qy      61 FAKALNCKELTPEHEPCNQCCVCKEISSGTSLDVIEIDGASHRGIEDIRQINETVLFTPA 120
           ||||||  |: : ||||||  ||||:||:||||:||||||||||||||||||||||||||
Db      61 LAKALNCVHLSEDGEPCNQCFSCKEIASGSSLDVLEIDGASHRGIEDIRQINETVLFTPV 120

Qy     121 KSQYKIYIIDEVHMLTKEAFNSLLKTLEEPPSHVKFFLATTENYKIPSTILSRCQKMHLK 180
           |:::|||||||||||||||:|||||||||| ||||| |||| :||| ||||||||||:
Db     121 KAKFKIYIIDEVHMLTKEAFNALLKTLEEPPQHVKFFFATTEIHKIPGTILSRCQKMHLQ 180

Qy     181 RIPETMIVDKLASISQAGGIETSREALLPIARAAQGSLRDAESLYDYVIGLFPTSLSPEL 240
           ||||  |::||:::|   || |:||| ||||||||||||||||||| ||| ||||:
Db     181 RIPEKTILEKLSLMAQDDHIEASQEALAPIARAAQGSLRDAESLYDYVISLFPKSLSPDT 240

Qy     241 VADALGLLSQDTLATLSECIRTQKYAEALLPVTTAINSGVAPITFLHDLTVFYRDVLLNK 300
           ·|| |||  |||:| ||  |  : || ||  ||  :||||||:|||||||:|||::||
Db     241 VAQALGFASQDSLRTLDNAILQRDYATALGIVTDFLNSGVAPVTFLHDLTLFYRNLLLT- 299

Qy     301 DQGNSPLSAIAMHYSSECLLEIIDFLGEAAKHLQQTIFEKTFLETVIIHLIRICQRPSLE 360
             ||  |  :  | :| ||||||||||:||||| ||||:|||||||||:||| ||| |
Db     300 ---NSTTSKFSSQYKTEQLLEIIDFLGESAKHLQNTIFEQTFLETVIIHIIRIYQRPVLS 356

Qy     361 TLFSQLKTSTFDTVRNVPQ---QQEPSKPSIQPEKHYQDQSFL---TSPSPTPKVQHQKE 414
           | | :|:  |: :||: :    |: | |  ||:  |::||||     |:  |:  :
Db     357 ELISSIKSRQFEGLRNIKEPTLTQQVSAP--QPQPTYKEQSFLEKKNQPAAEGKIISVEV 414
```

Qy 415 ASPSLVGSATIDTLLQFAVVEFSGIL 440
| : : || :||||||||||||||||
Db 415 KSSASIKSAAVDTLLQFAVVEFSGIL 440

The structure of the elected sequences (SEQ ID Nos 11 and 13) have 46.4% and 62.8% sequence identity, respectively with the family glu-tRNA amidotransferase C chain of polypeptides from *Chlamydia pneumoniae*. See the sequence alignments below:

SEQ ID NO: 11, C;Superfamily: probable glu-tRNA amidotransferase C chain

Query Match 46.4%; Score 91; DB 2; Length 100;
Best Local Similarity 35.9%; Pred. No. 0.00018;
Matches 14; Conservative 14; Mismatches 11; Indels 0; Gaps 0;

Qy 3 IQEYESSLNEVIKTMAASIAMDVTDVVIEVGLSHVISPE 41
::|: :|:|:|| | ||:|::|:::| : | : ||
Db 27 VEEFVTSMNDVIALMQEVIAIDISDIILEATVHHFVGPE 65

C;Superfamily: probable glu-tRNA amidotransferase C chain

SEQ ID NO: 13, Query Match 62.8%; Score 301; DB 2; Length 100;
Best Local Similarity 56.0%; Pred. No. 5.8e-21;
Matches 56; Conservative 24; Mismatches 20; Indels 0; Gaps 0;

Qy 1 MTQPYVTREDIILLAKSSALELSEEFIQEYESSLNEVIKTMAASIAMDVTDVVIEVGLSH 60
||: || :|:|| |||::|||| : ::|: :|:|:|| | ||:|::|:::| : |
Db 1 MTESYVNKEEIISLAKNAALELEDAHVEEFVTSMNDVIALMQEVIAIDISDIILEATVHH 60

Qy 61 VISPEDLREDIVASSFSREEFLTNVPESLGGLVKVPTVIK 100
: |||||||:| | |::||||:||| ||||||||||||
Db 61 FVGPEDLREDMVTSDFTQEEFLSNVPVSLGGLVKVPTVIK 100

The state of the art regarding DNA Pol III gamma and Tau subunits and amind-transferase (C subunit) (gene C gene) are described below:

McHenry *(Molecular Microbiology 2003, 49(5), 1157-1165)* teach that genome sequencing studies have revealed that low GC content gram-positive bacteria have two polymerases. McHenry teaches that one type is prototypical gram-positive bacterial PolC which is characterized by a catalytic subunit with proofreading exonnuclease activity and the second is polymerase is homologous to the α subunit of *E. coli* Pol III (DnaE). Genetic analysis indicate that both polymerases are essential for viability (pages 1162-1163). Therefore, the skilled artisan would conclude from the review of the cited art that this polypeptide is not an outer-membrane protein and internal to *Chlamydia psittaci* and is involved in transcription.

Curnow et al (*Proc. Natl. Acad. Sci., Vol. 94, October 1997, p. 11819-11826)* teach that three genes gatC, gat A and gatB constitute the transcriptional unit of gram-positive bacteria (see the Abstract). Raczniak et al *(The Journal of Biological Chemistry)* teach that GatC if the most divergent subunit for which no function can be suggested by homology searches (page 45867). Raczniak et al teach that it was proposed that GatC is required for proper expression or folding of the GatA subunit (page 45867). Therefore, the skilled artisan would conclude from the review of the cited art that this polypeptide is not an outer-membrane protein and internal to *Chlamydia psittaci* and is involved in transcription.

The specification has failed to teach or disclose how the data in figure 5 correlates to protection assays. Thus, one skilled in the art cannot conclude that there is a correlation between protective immunity and the claimed method of immunizing animals using the claimed polypeptides as set forth in SEQ ID Nos: 7, 9, 11 and 13 since there is no unvaccinated control data presented and the skilled artisan cannot drawn in conclusive evidence from the data presented in the instant specification.

The prior art as cited above has taught that DNA pol III gamma and tau as well as gatC are enzymes which are involved in transcription. These proteins are not known in the art as being potential antigens to protect against *Chlamydia* or any other bacterial infections. In fact, the art teaches that the function of GatC is unknown. Based on the instant specification the skilled artisan would not reasonably conclude that the claimed method is enabled. As, state above, it is unclear how Applicant interprets the data present in for example, Figure 5, since no unvaccinated control is present and the data is disclosed in the terms of maximum protection.

Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record

establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with regard to data present which correlates to protection assays in which the claimed method has been practiced, 3) there are no working examples are not specific to particular antigen used in the claimed method of immunizing an animal, 4) the relative skill of those in the art is commonly recognized as quite high (post - doctoral level), and 5) the state of the art in the field to which the invention pertains is recognized in the art as evidenced by the cited prior art.

In view of all of the above, in view of the lack of guidance provided in the specification, it is determined that it would require undue experimentation to make and use the claimed invention. Applicant is asked to place on the record, what they intend by the data present in figure 5.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 74 is depend upon claim 25 which is a cancelled claim. Claim 74 is indefinite because there is no text for claim in which it depends. Correction is required.

Status of Claims

5. No claims allowed. The closet prior art to the claimed invention is Griffais et al *(WO 99/28475 published June 10, 1999 and U.S. Patent No. 6,559,294 published May 6, 2003)* which both teach a *Chlamydia* polypeptide that comprises fragments of the

polypeptides as set forth in SEQ ID Nos: 7 and 9. See SEQ ID No: 59 of the prior art. Griffais et al also teach *Chlamydia* polypeptide that comprises fragments of the polypeptide as set forth in SEQ ID No: 13. See SEQ ID N:12 of the prior art. The prior art does not disclose the *Chlamydia psittaci* antigens as set forth in SEQ ID Nos: 7, 9, 11 and 13 nor does Griffais et al disclose a method of immunizing an animal using the *Chlamydia psittaci* antigens as set forth in SEQ ID Nos: 7, 9, 11 and 13.

Conclusion

6. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew, can be reached at (571) 272-0787.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
February 1, 2007

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER